

CLINICAL TRIAL RESULTS



Researchers look at the results of many studies to decide which treatments may offer patients improvements in terms of efficacy and safety. It takes people taking part in many studies around the world to help researchers decide this. This summary only shows the results from this study. Other studies might have different results.

Sponsor	BeiGene, Ltd.
Medicine(s) Studied	Tislelizumab (BGB-A317)
Protocol Number	BGB-A317-311
Dates of Study	June 2019 to March 2025
Title of This Study	A Study to Compare Tislelizumab (BGB-A317) Versus Placebo in Combination With Chemotherapy and Radiation Therapy in Adults With Esophageal Squamous Cell Carcinoma (ESCC)
Date of This Report	March 2026

Thank You!

BeiGene, who managed this study, thanks the study patients for taking part in the clinical study for a new medical treatment called tislelizumab. In this study, researchers learned more about the safety and efficacy of tislelizumab, also called BGB-A317, and how it may work in patients with esophageal cancer.

BeiGene thinks it is important to share the results of the study with the public. If you participated in the study and have questions about the results, please speak with the doctor or staff at your study center.

Why was this study done?

Researchers are looking for better ways to help people with **advanced esophageal cancer**. Esophageal cancer is cancer that starts in the esophagus. Mutations or changes to the DNA can cause cells to grow out of control and form a tumor. There are two types of esophageal cancer, adenocarcinoma, which starts in the gland cells at the bottom of the esophagus closer to the stomach, and squamous cell carcinoma, which starts from squamous cells mostly in the upper esophagus.

Most esophageal cancers do not cause symptoms until they have grown large or spread to an advanced stage. The symptoms and signs of esophageal cancer may include trouble swallowing, pain in your throat or chest, vomiting or coughing up blood, heartburn, hoarseness or chronic cough, and unintentional weight loss.

In this study, researchers wanted to learn more about how safe tislelizumab is when given in combination with chemotherapy and radiation therapy, and how it works in patients with **localized esophageal squamous cell carcinoma (ESCC)** that is unsuitable for surgery. Participants may have previously received less than three cycles of prior chemotherapy without radiotherapy. Localized means the cancer may have spread into nearby tissue or some lymph nodes but has not spread to other parts of the body.

Tislelizumab is a protein that strongly binds to a protein called PD-1 (also called programmed cell death-1) which is found on the surface of certain immune cells called T-cells. When tislelizumab binds to PD-1, it helps the T-cells to recognize and attack cancer cells.

Before a new medical treatment can be approved for use in patients, researchers must conduct clinical studies to learn how safe the treatment is by looking at adverse events, or side effects, and how well the treatment works. Adverse events are unwanted medical problems patients can experience that may or may not be caused by the treatment.

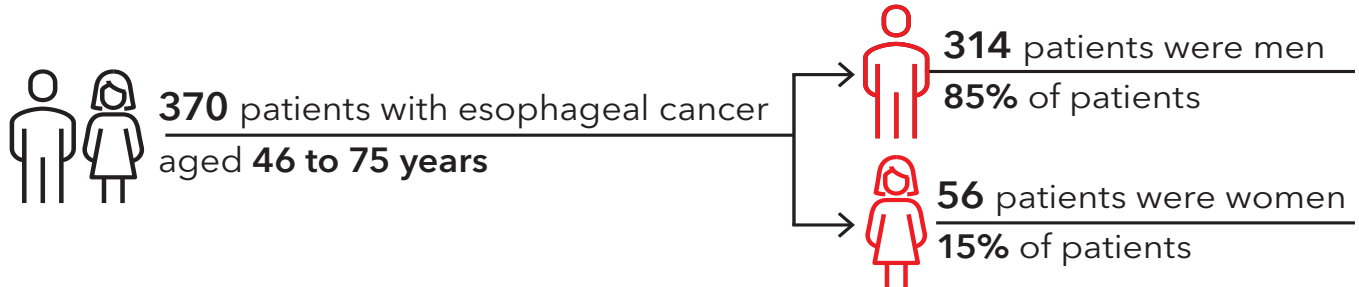
Researchers in this study wanted to know:

- ▶ What adverse events would patients who took part in this study have?
- ▶ How long did participants in the study live without their cancer growing or spreading?



Who was in this study?

A total of 370 patients ranging in age from 46 to 75 years were in the study. There were 314 men (85%) and 56 women (15%):



When and where was this study done?

This study started in June 2019 and ended in March 2025. The study was conducted at 32 study centers in China.

How was this study done?

In this study, patients with esophageal cancer were randomly assigned to one of two treatment groups:

- **Treatment Group 1:** tislelizumab with chemotherapy and radiation therapy
- **Treatment Group 2:** placebo with chemotherapy and radiation therapy

Neither the participant nor the study researchers knew whether each person was taking tislelizumab or placebo (this is called a double-blind study).

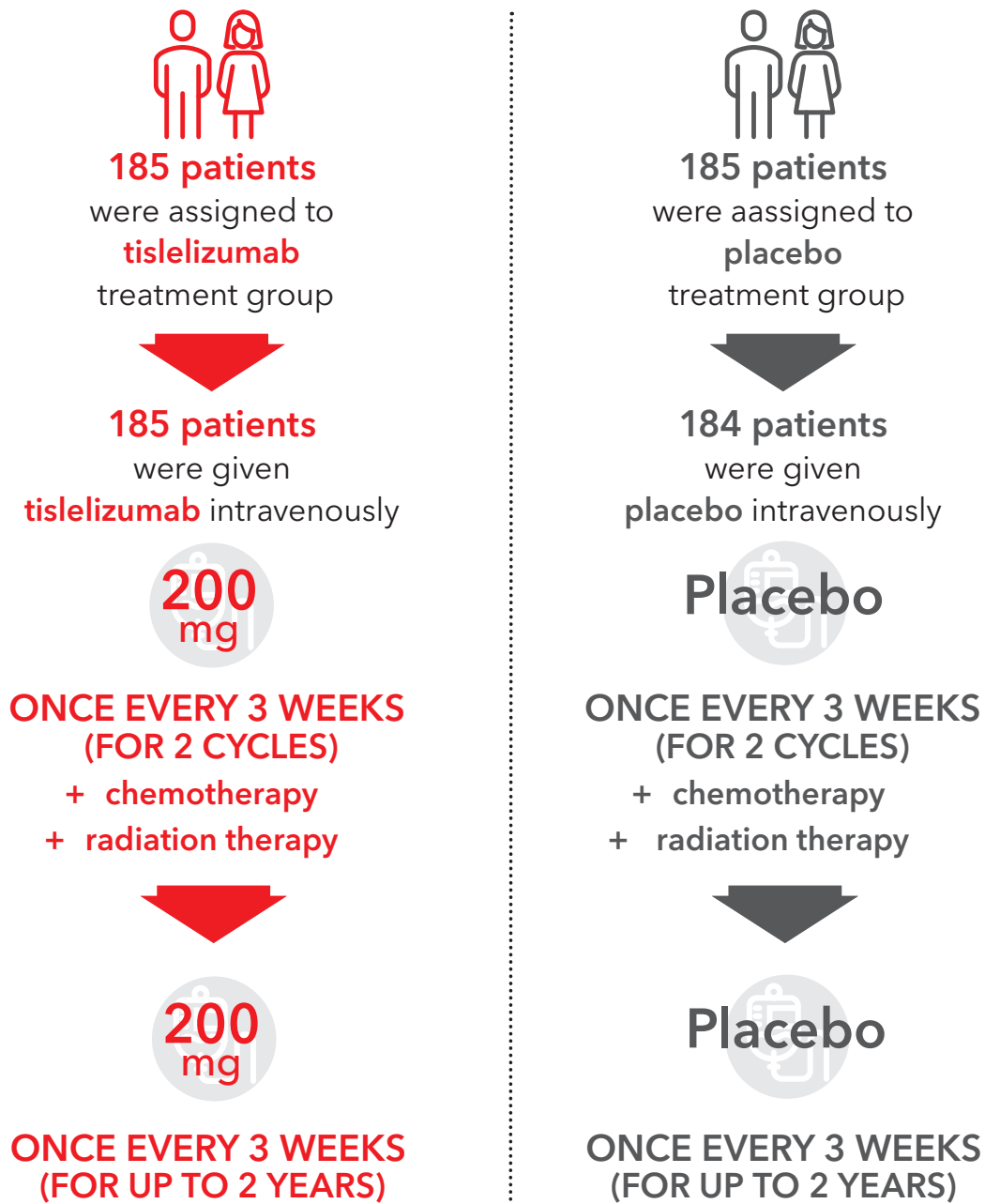
Participants in the tislelizumab group received 200 milligrams (mg) of tislelizumab through an infusion into a vein plus chemotherapy every 3 weeks. Patients in the placebo group received placebo (saline solution) through an infusion into a vein plus chemotherapy once every 3 weeks.

Chemotherapy included the following two medicines:

- Cisplatin 25 mg/m² by intravenous (IV) infusion on the first 3 days of treatment cycle 1 and 2. Each treatment cycle was 3 weeks
- Paclitaxel 135 mg/m² by IV infusion on the first day of treatment cycle 1 and 2. Each treatment cycle was 3 weeks

Participants also received radiation therapy 5 days a week for the first 6 weeks (a total of 50.4 Gray (Gy) over 28 sessions).

Participants stayed on tislelizumab or placebo until their cancer got worse or until they needed to stop the treatment due to health problems.



During the study, the trial doctors

- Did physical exams and checked the participants' vital signs
- Looked at computed tomography (CT) scans or MRI scans (called magnetic resonance imaging) to check the participants' tumors
- Asked the participants how they were feeling and how bad their symptoms were
- Monitored patients closely for any side effects

To learn how long study participants lived without their ESCC growing or spreading, the study doctors looked at images of the patients every 9 weeks for the first year and then every 12 weeks after that. The amount of time participants live without their cancer spreading is called **Progression-free Survival**.

What adverse events did the study participants have?

Adverse events are medical problems that may or may not be caused by the study treatment. An adverse event is called “serious” if it causes long-lasting problems, puts the participant in the hospital, is life-threatening, is considered medically important by the study doctor, or leads to death. A total of 369 participants were evaluated for adverse events.

- 100% of participants had at least 1 adverse event
- 40% of participants had serious adverse events
- 25% of participants had an adverse event that caused them to stop treatment

The websites listed at the end of this summary may have more information about the adverse events that occurred in this study.

What serious adverse events did participants have?

Pneumonia was the most common serious adverse event. The most common serious adverse events that occurred in at least 2% of the participants in any treatment group are shown here:

Serious adverse event	Tislelizumab + CRT (Out of 185 patients)	Placebo + CRT (Out of 184 patients)	Total (Out of 369 patients)
Pneumonia (an infection in the lungs)	10.8% (20 participants)	4.3% (8 participants)	7.6% (28 participants)
Immune-mediated lung disease	7.6% (14 participants)	1.1% (2 participants)	4.3% (16 participants)

Serious adverse event	Tislelizumab + CRT (Out of 185 patients)	Placebo + CRT (Out of 184 patients)	Total (Out of 369 patients)
Decrease in platelet counts	3.2% (6 participants)	1.6% (3 participants)	2.4% (9 participants)
Blockage or narrowing of the esophagus	2.7% (5 participants)	2.7% (5 participants)	2.7% (10 participants)
Difficulty swallowing (dysphagia)	2.2% (4 participants)	0.5% (1 participant)	1.4% (5 participants)

Nine participants (2.4%) had adverse events that led to death. None of the adverse events that led to death were thought to be caused by tislelizumab or placebo.

What were the most common adverse events?

A decrease in white blood cell count was the most common adverse event. The most common adverse events that occurred in at least 30% of the participants in any treatment group are shown here:

Adverse event	Tislelizumab + CRT (Out of 185 patients)	Placebo + CRT (Out of 184 patients)	Total (Out of 369 patients)
Decrease in white blood cell count	80% (148 participants)	82% (150 participants)	81% (298 participants)
Anaemia (low red blood cells)	75% (139 participants)	76% (139 participants)	75% (278 participants)
Decrease in neutrophil count	69% (128 participants)	74% (136 participants)	72% (264 participants)
Decrease in platelet count	50% (93 participants)	46% (85 participants)	48% (178 participants)

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Adverse event	Tislelizumab + CRT (Out of 185 patients)	Placebo + CRT (Out of 184 patients)	Total (Out of 369 patients)
Nausea	48% (89 participants)	41% (75 participants)	44% (164 participants)
Inflammation of the esophagus caused by radiation therapy	47% (87 participants)	53% (98 participants)	50% (185 participants)
Decrease in weight	45% (84 participants)	32% (59 participants)	39% (143 participants)
Constipation	36% (67 participants)	36% (66 participants)	36% (133 participants)
Decrease in appetite	36% (67 participants)	30 (55 participants)	33% (122 participants)
Low albumin levels (Hypoalbuminemia)	36% (66 participants)	38% (69 participants)	37% (135 participants)
Low potassium levels (Hypokalemia)	36% (66 participants)	26% (47 participants)	31% (113 participants)
Decrease in lymphocyte count	35% (65 participants)	38% (70 participants)	37% (135 participants)
Vomiting	34% (63 participants)	25% (45 participants)	29% (108 participants)
Low sodium levels (Hyponatraemia)	32% (60 participants)	25% (46 participants)	29% (106 participants)

What were the main results of the study?

The main results of the study are summarized here. The results for each participant in the study are not shown here and may be different from the overall results.

You can find a full list of the questions for this study on the websites listed on the last page of this summary. If there are results already available, they will also be found on these websites.

How long did participants in the study live without their cancer growing or spreading?

Researchers wanted to know how long participants lived without ESCC getting worse after starting study treatment. To learn this, researchers measured the median **progression-free survival**. Median progression-free survival is the amount of time at which half of the study participants lived without their cancer growing or spreading and the other half of participants had their cancer grow or spread.

The researchers looked at the time from the start of the study treatment until January 2025 (about 5 years). During this time, the median **progression-free survival** was about 29 months for participants in both treatment groups.

How has this study helped people and researchers?

The results from this summary will help researchers and patients understand more about how tislelizumab works in patients with ESCC and may provide additional treatment options for patients in the future.

More studies with tislelizumab are ongoing for other types of cancer.

The results in this summary are from this one study. Other studies may show different results. If you participated in this study and have questions about the results, please speak to the doctor or staff at your study center. You should not make changes to your treatments based on the results of this study.

Where can I find out more about this study?

More information about this study, including any available results, is found below:

The full title of this study is

A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study of Tislelizumab (BGB-A317) Versus Placebo in Combination With Concurrent Chemoradiotherapy in Patients With Localized Esophageal Squamous Cell Carcinoma

The protocol number is

BGB-A317-311



For information
about this study
in the United States

[Click here](#) 



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about this study in
China

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Clinical study participants help researchers make important discoveries that may lead to new medical treatments worldwide. BeiGene sponsored this study and is thankful for the help of the patients in this study.

For more information about BeiGene:

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